

Historic, Archive Document

Do not assume content reflects current scientific knowledge, policies, or practices.

Reserve
aQH442
.L37
1992

**United States
Department of
Agriculture**



National Agricultural Library

GENETICALLY ENGINEERED ANIMALS: ISSUES AND CONCERNS

An Interview Study

July 8, 1992

Dr. Alvin L. Young
USDA, Office of Agriculture
Room 1001 RPEP
1631 N. Kent Street
Arlington, VA 22209

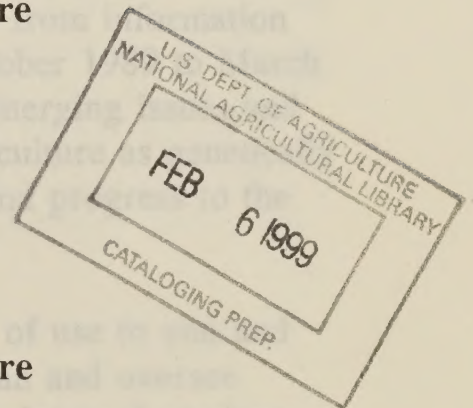
Prepared by

Jean A. Larson

Supervisory Technical Information Specialist
United States Department of Agriculture
National Agricultural Library

Submitted to

Dr. Alvin Young
United States Department of Agriculture
Office of Agricultural Biotechnology



The information contained in this report does not necessarily represent official policies, positions, or concerns of the United States Department of Agriculture.

Jean A. Larson, Coordinator
Animal Welfare Information Center

July 1992



Animal Welfare Information Center

National Agricultural Library
10301 Baltimore Boulevard
Beltsville, Maryland 20705

July 8, 1992

Dr. Alvin L. Young
USDA, Office of Agriculture
Room 1001 RPEP
1621 N. Kent Street
Arlington, VA 22209

Dear Dr. Young:

I am pleased to transmit to you the enclosed report "Genetically Engineered Animals: Issues and Concerns". The report was prepared from information gathered during a 6 month work detail to your office--October 1989 to March 1990. The goal of the project was to gather and present emerging issues and concerns that will impact on the U.S. Department of Agriculture as genetically engineered animals emerge from the research laboratory and progress to the market place.

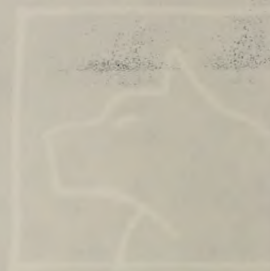
I hope that the information presented in the report will be of use to you and your colleagues as you develop guidelines and policies, plan and oversee biotechnology research, evaluate product safety, plan for release of products, and address the public's concerns.

Sincerely,

Jean A. Larson, Coordinator
Animal Welfare Information Center

Animal Welfare Information Center

National Agricultural Library
10303 Baltimore Boulevard
Beltsville, Maryland 20705



July 1, 1992

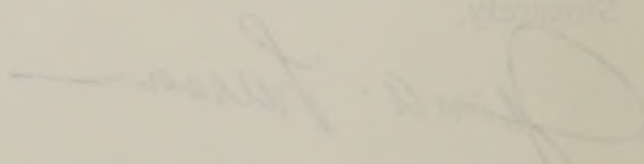
Dr. Anne E. Young
FDA, Office of Agriculture
Room 101 B-1
1651 N. Kent Street
Annapolis, VA 20709

Dear Dr. Young:

I am pleased to transmit to you the enclosed report, "Domestically Bred and
Adapted Inbred and Consanguineous". The report was prepared from information
gathered during a 6 month study held in your office October 1991 to March
1992. The goal of the project was to gather and present summary data and
conclusions that will assist in the U.S. Department of Agriculture in providing
organized scientific evidence from the research literature and to provide to the
public place.

I hope that the information presented in the report will be of use to you and
your colleagues in your domestic production and genetic plan and strategy.
Information presented, without further study, plus the release of information,
and address the public interest.

Sincerely,


Lynn A. Larson, Chairman
Animal Welfare Information Center

1. ISSUES REGARDING GENETICALLY ENGINEERED ANIMALS

EXECUTIVE SUMMARY

Animal Care. The major concerns included oversight of animal research protocols - especially critical questions about whether

Definition: Genetically engineered animals are created when novel DNA sequences are transferred and incorporated into the DNA of an animal.

of novel animal strains, taxonomy and classification of the animals, and unique husbandry requirements.

The engineering of the genetics of food and livestock animals by the introduction of foreign DNA has the potential to impact on many and diverse segments of our culture and environment. To explore these potential impacts Dr. Alvin L. Young of the Office of Agricultural Biotechnology of the USDA provided the author with the opportunity to do a special ethics/issues related project regarding genetically engineered animals. The project was to interview about twenty individuals from a wide variety of institutions and disciplines about the potential impacts as they perceive them. The information provided was to be compiled and presented to Dr. Young as a report. The interview portion of the study took place between October 1989 and March 1990.

industry.

During the interviews 2 questions were asked every interviewee regarding USDA policies and programs. (1) "If you were a USDA administrator managing programs involving genetic engineering research and food product safety, what are the issues you feel that you would have to address?" (2) "What advice do you have for such an administrator regarding transgenic animal research and the resulting products?" Other questions were generated spontaneously during the interview.

Regulations. The question of whether to regulate the process or the product was considered very important. Some individuals were worried that the U.S. policies were being developed too slowly and therefore the other countries would develop their own. If this scenario develops, unresolvable issues/lack of harmony could

RESULTS

The information provided by those interviewed generally dealt with the following subject areas: animal care issues; governmental and academic research concerns; patenting issues, human health and safety issues, potential economic impacts; possible ecological and environmental effects; religious, and general societal concerns; communication concerns, and various recommendations to the administrators of U.S.D.A.

I. ISSUES REGARDING GENETICALLY ENGINEERED ANIMALS

- ◆ **Animal Care.** The major concerns included oversight of animal research protocols - especially ethical questions about whether research is needed, pain control, and euthanasia guidelines. Questions were raised regarding the responsibilities for maintenance of novel animal strains, taxonomy and classification of the animals, and unique husbandry requirements.
- ◆ **Research.** Currently there are 3 directions of animal research (1) the production of biologicals, (2) genetic immunity to important diseases, and (3) increased feed efficiencies of meat producing animals. Responsible oversight of research was strongly recommended. There was a suggestion to consolidate this type of research into only a few centers, and to fund studies on the potential resulting environmental and social issues. Academia may need to address scientific merit, potential liability suits, patent policies, and the control of research that is funded by private industry.
- ◆ **Patenting.** The enablement requirements for patenting animals may be difficult to overcome, due to the variability of insertion of foreign DNA into the host. Increased costs of patented animals, ultimately passed on to the consumer, and the farmers' exemption were raised.
- ◆ **Regulations.** The question of whether to regulate the process or the product was considered very important. Some individuals were worried that the U.S. policies were being developed too slowly and therefore the other countries would develop their own. If this scenario develops, unresolvable issues/lack of harmony could restrict U.S. biotech products in the world marketplace.
- ◆ **Human Health and Safety.** The safety of meat products from altered animals will depend on changes in composition due to gene location insertion effects, the physiological effects, and the product or products of the novel gene. Orally active compounds (those that

pass through the stomach unchanged) could present a health hazard. Rigorous safety testing will be needed to allay fears. Labelling requirements for transgenic food products may need to be developed. Ethical concerns regarding the use of human genes in food products will need to be addressed.

- ◆ **Economics.** Major changes in agricultural systems for accommodating to various novel livestock species are projected. Will the banking industry be willing and able to underwrite the changeovers to novel and untested systems? Research regarding consumer preferences/choices and potential economic impacts on the farming community was recommended.
- ◆ **Ecology.** Potential ecological effects resulting from the mixing of genetically engineered and feral populations of animals was a concern. Large animals are easily contained, but fish may present problems. Expanded ranges of aquaculture systems due to genetic engineered qualities could cause environmental changes in aquifers and drainage systems, lethal challenges to indigenous populations, and changes in water fowl populations and ranges.
- ◆ **Religious and General Societal Concerns.** A variety of cultural and religious concerns and questions were raised regarding the technology itself apart from the engineered animals. Pluralism of the U.S. population virtually eliminates a consensual acceptance of policies. Some people feel that species are "God's work" and should not be "tinkered" with! Will religious leaders understand the technology and express support and confidence in the scientists' ability to adequately control the directions of this technology? The blurring of species boundaries - especially between humans and primates may be a dominant concern. Public understanding of such concerns will enable the Department to communicate effectively with leaders who influence the public.
- ◆ **Education and Communication.** Every interviewee was concerned about the quantity and quality of communication efforts between the USDA and the public. The lack of understanding of science by the general public is seen as a powerful barrier to

effective communication and potential acceptance of biotech products. Suggestions for improving communication are (1) educate the media personnel, (2) utilize multiple-source educational materials, (3) sponsor education programs and projects directed to the public, and (4) expand the role of the Extension Service in communicating to educate the public.

II. ADVICE REGARDING USDA PROGRAMS AND ADMINISTRATION

- ◆ **Research and Safety.** Research should be sponsored on the greater understanding of consumer perceptions, food animal product acceptance, societal decision making, and philosophical/cultural operatives. ARS and CSRS should coordinate interdisciplinary research on the safety of foods, hardiness of homozygous animals, structure of animal genomes, effects of costs on the agricultural community and the consumer.
- ◆ **USDA Programs.** Overwhelmingly, interviewees felt that USDA should expand educational programs to raise the scientific literacy of the U.S. population. Suggested audiences (listed in priority order) are: (1) students, (2) farmers, (3) authors for non-scientific literature and (4) the general public. "Ag in the Classroom", (a USDA program) should be expanded to reach elementary and secondary students. Information generated for trade magazines and extension activities can be used to reach farmers. New approaches should be developed to reach the media and ultimately the public.
- ◆ **Policy.** Federal guidelines should be developed specifically for genetic engineering research in animals. Issues addressed should include euthanasia, analgesics, facility security needs, physical plant requirements, personnel training, and potential biohazard. Media communication policies should stress candor, and unbiased information to maintain the public's trust. Policies, regulations or programs should be carefully structured to address public fears and concerns and to protect human health and the environment.

- ◆ **USDA Communication.** The interviewees offered several "do's and don't's" for USDA spokespersons consideration. There were suggestions that communications should deal with the scientific issues and not the emotional issues. Administrators should understand the role of the activists in social issues so that adequate responses can be formulated.

This report is not considered to be a definitive treatment of the topic but rather a starting point for dialogue on potential issues of the emerging technology as it relates to animals.

ACKNOWLEDGEMENTS

Obviously, this project reflects the contributions of many people other than the author. I am particularly grateful to Dr. Alvin Young, Director of OAB and to Mr. Joseph Howard, Director of the National Agricultural Library for the opportunity to pursue this interesting project.

I am also indebted to the AWIC staff. They managed The Animal Welfare Information Center "picked up the slack" and managed Center affairs just fine while I was out of the office for 2 days every week for 6 months. I would also like to thank Dr. Paul Thompson of Texas A & M and Dr. Lowell Owens of USDA's Agricultural Research Service for their excellent editorial reviews, while Jennifer Lyons-Carter, Tim Allen and Katie Shull of AWIC deserve special thanks for helping to get the manuscript in order.

Obviously, I depended on the candor, goodwill and interest of the interviewees who participated in the project. My sincere thanks goes to those individuals who gave freely of their time, expertise, and thoughts regarding the genetic engineering of animals. I hope they feel as I do, that it was time well spent.

Jean A. Larson
Beltsville, MD
1992

TABLE OF CONTENTS

Executive Summary	i
Acknowledgements	vi
Introduction	1
Materials and Methods	3
Results of Interviews	
Issues Regarding Genetically Engineered Animals	5
Advice Regarding USDA Programs and Administration	23
Appendix A	29

INTRODUCTION

Genetically engineered or transgenic animals (GEA's) are created when novel DNA sequences are transferred and incorporated into the DNA of an animal. Why are these techniques being applied to animals and what roles are such novel animals expected to play in agriculture? As expressed by Palmitier (1986)¹ "Gene transfer is especially valuable in diploid organisms with long life cycles where classical approaches [to animal breeding] are impractical".

What are the potential applications in animals? Possibly--

- ◆ faster growth.
- ◆ repartitioning of energy into protein instead of fat.
- ◆ "precious proteins"--pharmaceuticals/biologics.
- ◆ physiological alterations for new environments.
- ◆ resistance to economically important diseases.
- ◆ compositional changes in secretions such as milk.
- ◆ basic understanding of biological functions and systems.

The 7 research applications stated above do not in themselves reveal the potential breadth of the impacts likely to result as transgenic animals are introduced into our culture. The following list of impacts (generated by the author) is designed to illustrate the potential broad effects on various sectors of our society. (The listing is not intended to be definitive. The reader is encouraged to expand the list due to his or her unique perspective.)

- ◆ Administrators of research programs will be challenged to evaluate and approve research protocols using genetic engineering technologies.

¹Palmiter, R.D. and Brinster, R.L. 1986. "Germline transformation of mice." *Annual Reviews of Genetics* 20:465-499.

- ◆ Researchers will have a powerful methodology for creating an array of truly novel animals.
- ◆ Social scientists will have the opportunity to study a technology from concept to application including governmental policy decisions and public responses.
- ◆ Philosophers and ethical/moral leaders will have many issues generated by transgenics for discussions of ethical decision making or moral dilemmas.
- ◆ Political activists will have new issues to use to exploit peoples fears.
- ◆ Educators will need to develop new curricula.
- ◆ Animal producers will face new challenges in husbandry and investments.
- ◆ Economists will need to study and predict the potential viability of new products, and markets.
- ◆ Businesses will be faced with problems of technology transfer, product development, research expenditures, and entrepreneurial adventures.
- ◆ Policy makers and the public will be forced to develop an awareness of potential products of this new technology, and assume responsibility for consumer protection and safety, protective guidelines and regulations, etc.

The potential effects will be far reaching!

Because so many facets of our society will be affected by the reality of GEA's, obviously, USDA activities and policies will be affected by this new technology as well. USDA administrators will have to make decisions regarding the allocation of research funds, guidelines for research oversight and intentional release, and the development of policies and protocols to insure the health and safety of edible products. With these potential impacts on the horizon, the USDA and other government agencies face significant policy

development decisions in the near future.

It was with these potential impending impacts in mind, that an interview project was sponsored by USDA's Office of Agricultural Biotechnology (OAB). The project was conducted from October 1, 1989 through March 31, 1990. The goal of the project was twofold:

- (1) To gather a broad array of ideas, projections and opinions from people with unique perspectives, experience and research expertise regarding the genetic engineering technology as applied to animals and;
- (2) To write a report detailing the information provided by a number of interviewees regarding the potential and diverse impacts that they predict will result from the purposeful manipulation of the genomes of food animals.

Recommendations to USDA policy makers are also a part of the report. Hopefully, the reported responses, issues, and recommendations will be valuable to policy makers as they plan research programs, develop research policies and/or regulations, and respond to societal concerns regarding genetically modified animals.

The author has made an effort to accurately present the broad and divergent points-of-view offered for consideration and evaluation. Under such circumstances, there are probably issues that are controversial for the USDA included in this report.

The ideas, issues, projections, recommendations and presentations are those of the interviewees or the author and do not necessarily reflect any official position of the U. S. Department of Agriculture.

Materials and Methods

Currently, applications for GEA's and their intentional release are still subject to discussion regarding types of acceptable research and regulatory oversight for the environmental release and product safety. Since these issues are so important, 20 individuals currently organizing their thoughts on the potential impact of GEA's in our society were chosen to be interviewed. Due

to time and financial constraints, most interviewees were from the Washington, DC area.

The twenty individuals, who generously shared their time and thoughts, represented a broad spectrum of disciplines, but not every discipline that will be affected by these animals. In most cases the interviewees have dealt with, or will soon have to deal with, issues associated with transgenic animals. The following disciplines were represented.

USDA researchers - 3	Academic, animal researcher - 1
USDA research admin.- 2	Academic, philosopher - 1
USDA grants staff - 3	Academic, political sci. - 1
USDA food safety staff - 1	State biotechnology center - 1
USDA economist - 1	Lawyer - 1
USDA OAB staff - 1	Environmentalism (org.) - 2
Animal welfarist (org.) - 1	Industry spokesman (org.) - 1

To ensure that the opinions of each individual could be explored according to their unique perspective and areas of expertise there were only 2 questions asked of every interviewee:

(1) "If you were in a position of a USDA administrator managing programs involving genetic engineering research and food product safety, what are the issues you feel you will have to address?"

(2) "What advice do you have for such an administrator regarding genetic engineering applied to animal research and the resulting products?"

The interviews were not tape recorded to protect identities. Each interview was summarized and condensed by the author.²

This report does not follow the traditional scientific study format. The author attempted to transmit a condensed version of a wide variety of divergent and unique ideas and thoughts that were generated during the discussions with the interviewees. There were several difficulties in presenting such information. It is difficult to connect ideas smoothly, but I hope that each idea

² A copy of the interview data, without interviewee identification is available upon request.

is important enough to stand alone. Another difficulty is maintaining the voice of the interviewees. This leads to a repetition of words, e.g. interviewee, reported, suggested, recommended, presented, etc. Also note that percentages have not been used to weight ideas. Since the material presented varied dramatically from individual to individual, the author feels that all the information is of equal value. In some instances references to articles are provided for those who desire additional information a topic/issue. There is no discussion section. What is presented is limited to the information freely provided in the interest of educating interested people about the potential impacts of genetically modified animals.

The report is divided into 2 sections. Section I, "Issues Regarding Genetically Engineered Animals", deals with issues regarding GEA's such as animal care; governmental and academic research; patenting problems; regulatory concerns; human health and safety; potential economic impacts; ecological and/or environmental effects; specific religious, ethical and general societal concerns; and communication. Section II, "Advice Regarding USDA Programs and Administration", deals with recommendations and advice to USDA administrators. Unless otherwise stated, all quoted material came from interviewees. There is also an appendix that consists of a brief, selected bibliography on the various topics of the report.

Results of Interviews

I. ISSUES REGARDING GENETICALLY ENGINEERED ANIMALS

Animal Care and Welfare Concerns and Issues. Animal care concerns were raised regarding ethical oversight of research protocols and guidelines and oversight for alleviating painful conditions and/or euthanasia. Questions were raised about potential difficulties in the maintenance of novel animal strains, what criteria that may be used to classify GEA's as "monsters", and potential changes in husbandry systems for animals with altered physical structure physiologies. Several issues were identified regarding the care and maintenance of novel livestock: husbandry of functional and any severely defective animals, potential changes in housing facilities, and security of research areas.

Since the economic value of GEA's may be very great, there may be a tendency to ignore humane care issues. Therefore, it was recommended that guidelines be implemented to provide unbiased humane care decisions regarding euthanasia and analgesics to be considered as part of an organization's research protocols. Such guidelines would need to define and address the conditions that may require analgesics or euthanasia. However, one researcher, who has produced GEA's, did not see euthanasia as an issue because he feels that if an embryo survives intact to birth, it can be an important source of data in these early stages of the research. This individual did not discuss potential use of analgesics.

Chronic pain and distress issues were raised regarding the long term maintenance of novel animals deliberately designed for an intentional loss of function (e.g. breeding blind chickens to reduce pecking). Embryo storage may be an alternative to maintaining breeding populations to preserve genomes, but these techniques still have yet to be developed for many species. In the event archiving of frozen embryos becomes a reality, the other issues such as the ethical issues of maintaining embryo source breeding colonies of animals that may have painful conditions will have to be addressed.

The issue of "monstrous creations" usually emerged in the conversations. Most peoples use of the term "monster" conjures up images of dramatic, frightening departures in looks, stature or temperament. One of the 1st USDA animals, the transgenic "Beltsville Pig", was placed in the "monster" category by some animal welfarists due to its crossed eyes, lethargy, and arthritic legs. Even so, a scientist expressed the opinion that considering the broad range of physiological effects of growth hormones, "'it' [the pig] was surprisingly normal!" However, experiences in caring for transgenic pigs that have been produced to date indicate some of the potential husbandry problems of transgenic livestock, to the researchers that these animals can have weaker supporting tissues requiring different flooring for comfort. Body fat can be reduced to the point where these animals are only comfortable in a narrower than normal ambient temperature range; feed requirements may be unique for each novel animal type; susceptibility to disease may be higher; and reproductive capacities and management may be affected. In the case of those animals that are secreting "precious proteins", housing and behaviors may be severely restricted by excessive protection due to their economic value. This will certainly be the case for the foundation animals or "founders" of important

GEA lines. As one researcher said, "The animals will be closely managed and may be very well taken care of, but they will **not** lead normal lives [for the species]."

Research Issues. The philosopher described the differing levels of researcher responsibility when comparing traditional and new methods (genetic engineering) of modifying the genetics of animals as he sees it. In his view, genetic engineering techniques offer the researcher the ability to manipulate selected gene traits with more "finite control" thus providing direct responsibility for the traits in the organism. With selective breeding, the breeder had less control and therefore less direct responsibility for the outcome. He feels that the public has only a general awareness of the difference between the old and new methods, but may demand more scrutiny of gene altering research and food products.

What are the applications for using these techniques of more "finite control"? A USDA researcher, engaged in transgenic research described 3³ general types of applications of genetic engineering to livestock:

(1) **Pharmaceutical products.** Pharmaceutical applications to produce "precious proteins" (protein compounds that are too large to be made by commercial fermentation processes) will probably be the first successes. These applications will generally require the insertion of human gene clones to insure efficacy of the gene product in the human. To date many of the known genes are human which will enable this research to proceed more quickly. The lack of knowledge of livestock genomes will delay research in producing animal biologics.

(2) **Genetic immunity to common diseases.** A goal of many researchers will be to create animals that are genetically immune to catastrophic diseases. The development of such animals will reduce losses to producers due to disease. This application is also likely to be well received by the public.

(3) **Increased feed efficiencies.** Feed efficiency for food animals is

³Disease models were not mentioned, but conceivably the concept of creating models for human disease could also have been mentioned as an application.

controlled by multigenic traits. Understanding, isolation and control of these multi gene systems will be needed before this research can proceed to the desired results. The projections for transgenic animals to be available for marketing may be 10 to 20 years.

In general most of the interviewees felt research to genetically engineer animals should continue without interference. Several felt that the similarity of human and animal genomes did not warrant limiting/restricting the use of human genes in livestock. However, one viewpoint was that moving genes between species was "animal parasitism" and would probably increase the number of genetic deficiencies rather than alleviate them. This same person also felt that such techniques should be reserved to correct severe defects and/or to promote the health of endangered species and not for domestic or food animals.

A problem in the application of the technology to date has been an inability to determine insertion site in the host DNA. Additional knowledge for finite control of DNA insertion techniques is expected. Such finite control hopefully will lead to healthier animals and avoid deficiencies as mentioned above.

On the issue of faster growing and bigger animals, an academic researcher questioned whether the faster growth and larger body mass for livestock were still appropriate goals for the production of food animals. He felt that the whole animal should be studied in greater detail to achieve biological efficiency. Furthermore, he worried that this research will produce animals that are reproductively dysfunctional.

One person questioned whether genetic engineering research to produce disease resistant animals, "will solve the disease resistance problem or will the pathogens mutate as they have in the past?" If such disease resistance proves to be short lived, could the time, intellectual and financial resources have been better utilized?

It was projected that the largest commercial payoff may be in producing livestock for the production of human biologics or as biomedical models of human disease. (Biomedical models of human disease were seen by some as a double edged sword since such models may lead to an increase in the use of

animals in biomedical research and slow the movement to alternatives to animals as research subjects.)

Most interviewees suggested that research protocol review and oversight at the institutional level be controlled by a bioethics committee, whose responsibilities would include implementing federal, state and institutional guidelines. The economist felt strongly that such a committee should be multi-disciplinary in structure. He suggested that such a committee include economists, who could provide an understanding of tradeoffs. An academician agreed with the multi-disciplinary concept because he felt that molecular biology is too narrowly focused and that it is important to understand the whole animal and the potential environmental interactions. Other areas suggested for a committee to address are: expected outcomes of the research, euthanasia criteria, and source of the gene insert. (It was generally agreed that human gene sequences may be necessary for the production of efficacious human biologics, but because of potential societal issues were not recommended for food animals.)

An academician felt that the adequate funding of a number of "specialty centers" would be a more productive way to spend research dollars than a large number of small projects. He suggested that USDA funding agencies consider a consolidation plan, because he is worried that a fragmented funding approach would lead to fragmented research results.

In addition to research directly manipulating animal genomes, several individuals mentioned a need for funding research assessing the risks associated with the environmental release of transgenic animals, human health issues, ethical concerns, and public perceptions. Results of such research could assist USDA in developing policies and strategies that would allay the public fears.

Research facility security is a major concern for researchers. They all felt that there were inadequate levels of security at their facilities. Their concern seems justified in view of reported acts of facility vandalism and thefts of animals that have occurred at many facilities in the U.S. They wanted improvements to their physical plants for the safety of the experimental

animals, themselves and their records and data.⁴ Considerable investment may be needed for such upgrades. Interestingly, one researcher predicts that when/if transgenic animals reach production levels, the security issue for them on the farm may not be as important as they are at the research facility.

Recognizing that there are areas of overlap between government and academic research, there appear to be several unique issues regarding GEA research in academia. At one point Iowa State University administrators were worried that this type of animal research could produce Algeny (Rifkin 1984)⁵ type products, potential liability suits and patent problems. To address these concerns the administrators proposed that a bioethics committee be established. The committee would have reviewed all protocols describing genetic engineering of mammals for scientific merit. (In a personal communication from Dr. Marshall Phillips to the author, the Iowa State committee apparently has not been established.) The concept of a bioethics committee at the academic level may be a very appropriate way to deal with research issues and concerns unique to academia.

One individual expressed the following fears regarding the impacts of privately funded research at universities. Under such dual arrangements, who has oversight responsibilities--the university or the private company? Will these alliances pressure academic institutions to engage in product biased research? Is the objective role of university research compromised?

In summary there were a number of issues that were raised regarding research to produce GEA's. Three directions of applied research were described (1) the production of pharmaceutical products, (2) genetic immunity to common catastrophic animal diseases, and (3) increased feed efficiencies of meat producing animals. Suggestions were made to restrict such research to only a few centers due to the high cost of the research and to fund research in environmental and societal issues. Responsible oversight of research was

⁴To provide more protection for farm animals and biomedical research facilities, Congressman Charles Stenholm introduced a bill H.R. 2407 May 20, 1991. The bill is entitled "Farm Animal and Research Facilities Protection Act of 1991. Passage of this bill would make it a crime to illegally enter a farm or research facility with the intent to harm or steal the animals, obtain data and documents or destroy materials. To date it has not become law.

⁵Rifkin, J. 1984. *Algeny: A New Word - A New World* Penguin

strongly suggested. The unique issues faced by academic institutions are the review of protocols for scientific merit, the potential for liability suits, patent problems, and whether using private funds for GEA research compromises the public trust.

Patenting Issues. It was recognized that the U.S. Congress could pass legislation forcing the Patent and Trademark Office to eliminate the patenting of life forms all together or to limit the patenting to microbes or lower life forms.⁶ However, interviewers assumed that this would not happen, and this point of view was reflected in their comments, which dealt with two main issues: (1) the patenting process and (2) the effects of patenting on the farmer and the public.

Regarding the patenting process, several interviewees deemed it perfectly ethical to award patent protection for the creation of animate life forms, as well as for inanimate objects and processes.

Other issues involve criteria for patentability. Because patent examiners are more knowledgeable about molecular genetics and many human protein sequences have been published, the use of such sequences in animal genomes may be categorized as "not novel". The implication is that the criteria for determining a "new product", (an animal, in this case) appears to be blurring.

The patent lawyer explained that enablement, a critical factor in the patenting process, may become a limiting factor in the patenting of GEA's. (Enablement is the provision of information and/or material to ensure replication of a patented process or product.) Viability of stored components, and the potential for degradation as well as the unpredictability of biological raw materials raises a multitude of enablement questions.⁷ If enablement cannot

⁶ On April 28, 1992 Benjamin Cardin (D-MD) introduced H.R. 4989 to amend Title 35 of the United States Code to impose a 5-year moratorium on the granting of patents on invertebrate or vertebrate animals, including those that have been genetically engineered, so that Congress can fully assess, consider, and respond to the economic, environmental, and ethical issues raised by the patenting of such animals.

⁷ The author is aware of several issues: lack of methodologies and established facilities for storage, archiving, and guaranteed viability of animate materials, consistency or reliability of reproducing a whole organism from stored tissues, control of insertion location, and slight genetic variations in the recipient DNA.

be accomplished by in vitro storage, the maintenance of a colony for the production of offspring in perpetuity may not be feasible either.

As mentioned above, there were concerns raised regarding possible impacts of patented food animals on both consumers and farmers. An economic issue raised was the fear of increased economic costs of agricultural inputs in the marketplace. If one sector of the economic system increases input costs, logically production costs will increase. These increases will be reflected in higher consumer costs. The opposite was also projected--GEA's may lead to increased returns for the farmer, and lower prices for the consumer.

Another emerging issue is whether the concept of the "farmer's exemption" will be applied to transgenic farm animals. Representative Robert Kastenmeier⁸, a member of the 1990 Judiciary Subcommittee--Courts, Intellectual and Administration of Justice--had submitted a bill that would allow farmers to utilize patented animals under the same conditions as the "crop exemption" (known as the farmer's exemption) of the Plant Variety Protection Act (PVPA) (P.L. 91-577 approved December 24, 1970, 84 Stat. 1542-1559).⁹ There are 2 ways that industry can get the return on investment--(1) through a premium price or (2) an offspring royalty. The biotechnology industry sees the farmer's exemption as potentially undermining the industry because farmers could sell the patented animals to each other to recover their initial investment and generate some additional income. This would limit the industry's ability to collect a premium price or a royalty to recoup R & D investments and reduce

reproducing a whole organism from stored tissues, control of insertion location, and slight genetic variations in the recipient DNA.

⁸ Mr. Kastenmeier was not reelected in the Fall of 1990, therefore the future of the bill is unknown.

⁹Briefly in the PVPA, the farmer (Farmer 1) who buys a certified seed has the right to save seed for his use in subsequent years and to sell some of the seed to Farmer 2. Farmer 2 can grow the seed for crop use only. Some growers have abused the system by selling the certified seed at levels that have put seed companies out of business (communicated to the author by Dr. K. Evans of USDA, AMS). The Regulation and rules of practice (United States Plant Variety Protection Act of December 24, 1970 (84 Stat 15420) (7 U.S.C. 2321 et seq. Regulation and Rules of Practice, Effective April 20, 1989) lack a definition for the concept of a farmer. For a concise review of the issues of the "farmers exemption" see Lerch Seed World, June 1989.

or eliminate product competition.

A lack of patenting protection for novel animals will likely lead to trade secrets by industry. (One individual felt that a trade secrets system will foster increased vertical integration and result in increased costs to everyone.) The industry spokesman also felt that farmers currently feel that only the large farmer will be able to afford such animals. Conceivably, these animals may not be accepted by farmers if they will require burdensome and expensive husbandry practices, additional paperwork, and genetic testing. (One individual felt that genetic profiles and patent infringement will be easier to identify with the use of restriction fragment length polymorphisms (RFPLs) or polymerase chain reaction technologies to identify the genetics of animals in question.) He expressed concern that lack of patenting protection for animals will lead to a brain drain of molecular geneticists to research disciplines where products would be patentable.

The patenting of animals has raised some very difficult issues surrounded by regulatory and legislative uncertainty. These uncertainties are reflected in the lack of consensus on several issues.

Regulations. The subject of regulations also generated conflicting responses. By regulations, the interviewees were referring to federal or state statutes that affect research, environmental release, product safety, trade, etc.

Although most interviewees felt that the present regulatory program was adequate, some mentioned that gaps (e.g. transgenic fish and pets) occur in the existing regulatory framework.¹⁰ To close the regulatory gaps, some groups are pressuring for comprehensive changes in federal oversight either by the formation of a new federal oversight body, or the placement of responsibility for oversight in one government agency--Environmental Protection Agency (EPA). Those who suggested that EPA should have the overall responsibility felt that USDA should not have any regulatory responsibilities. Another person felt that drastic changes in regulatory responsibilities would take at least five years to be sorted out, which would delay the transfer of the technology. Slowing the development of the industry could reduce U.S. competitiveness

¹⁰Under some circumstances non-federally funded research on animals does not fall under any oversight.

abroad.

The existing regulatory gaps are also generating state initiatives to formulate laws, e.g., North Carolina. As one individual expressed it, "if this is the beginning of a trend, then the ultimate result of states passing regulatory laws would be interference with interstate trade of biotechnology derived products leading to reduced economic growth for the industry."

It was strongly suggested by most interviewees that harmonization of worldwide biotechnology regulatory oversight and product safety issues needs to be addressed quickly by the U.S. Government. If such harmonization does not occur at all or does not occur soon enough, fears were expressed that U.S. products could be edged out of overseas markets. However, it was recognized that the process of harmonization may prove very difficult due to the diversity of cultures and international laws. It was suggested that possibly diversity may be reduced if the U.S. can produce adequate, comprehensive regulations, since such regulations might be adopted a model for other countries, thus simplifying the harmonization process.

Whether to regulate the **process** or the **products** of genetic engineering was raised by several people. They generally agreed that product safety is addressed by current regulations and policies, but there may be pressures from the public for additional regulatory control of genetically engineered products. Labelling requirements may need to reflect the genetic engineering aspects including but not limited to the source of the gene (human, fish, cattle, plant etc.) Providing the public with clear, easily understood information regarding products and how they are currently regulated will be extremely important in convincing the consumer that products, as currently regulated, are healthful and safe.

Health and Consumer Safety of Transgenic meat Products. An interviewee, knowledgeable about meat product safety, felt that two safety issues are raised by GEA products in the food chain: (1) the physiological role of the gene to be inserted and the effect of insertion location and (2) the gene product as expressed in the animals or animal product.

There are obviously a variety of compounds that can make meat products dangerous because of their effect on human physiology, but the example

provided was steroids. Steroids, as opposed to proteins, are described as orally active compounds passing unchanged through the gut. In the unlikely event that a gene effect produces increased steroid levels in an animal product, it could be serious. To prevent secondary compounds as contaminants in a transgenic meat product, consumer food products derived from GEA's will require rigorous testing to certify that products are free of dangerous levels of orally active compounds. The testing of untransformed (those that do not test carry the novel gene) litter mates resulting from current research might be the starting place for developing testing protocols to ensure product safety.

As mentioned in the regulatory section, society may demand more thorough safety testing which would affect federal food safety policies and protocols. An instructive example, mentioned several times, illustrated the power of the public when it perceives that a food product is not safe is the Alar scare of 1989-90.¹¹ To forestall such event from happening with products of GEA's, it was recommended that USDA be proactive in anticipating policy and educational needs before commercialization of these products.

Clearly, there are safety issues concerning meat from GEA's that need to be addressed with adequate and rigorous safety testing policies to allay public fears. The philosopher expressed the opinion that even if apparent risk issues are addressed, risk issues may not be the greatest concern for many people and assurances of risk free products may not completely relieve people's apprehensions. People may be apprehensive due to a fear of the unfamiliar or challenges to their intrinsic definition of what humans and animals and where lines of species are drawn. He put in a plea for more research to clarify the factors ("to separate the strands" as he poetically said) that might influence public behavior regarding biotechnology and biotech products. An understanding of the "strands" would allow USDA administrators to be better prepared to appropriately respond to issues and concerns, because the Department's responses to the public's fears may mean the difference between the success or the failure of engineered products in the market place.

¹¹ See Moore, J.A.; "Speaking of data: The Alar Controversy." EPA Journal 15(3):5-9 (1989), Rosen, J.D.; "Much ado about Alar." Issues in Science and Technology 7(1): 85-90 (1990) or Chou. M.; "Two years after the Alar crisis." Cereal Foods World 36(6):526-527 (1991).

Economic Aspects--the Producers. The farmers role as a producer generated a great deal of attention from the interviewees. Interviewees feel that the public is worried that changes like transgenics or BST will put farmers out of business. These worries are believed to be based on an outdated view of the "small farmer" in the American psyche. Now may be the time to educate the public about the reality of farming in the U.S. before they force laws and regulations to be passed that are not appropriate.¹² Ultimately, the producers will have to decide whether to invest in the engineered animals and the management systems to support them. The issues here are the predictable ones that affect most new products and technologies: costs of facility and management conversions, consumer product acceptance at a profit making level and availability of investment capital for unproven systems. Projected costs might be royalty fees, fees for genetic analysis of progeny, increased paperwork and bookkeeping for contractual control, utility costs for maintenance of temperature, and facility and animal security measures.

On the broader issue of animal production systems, the economist foresaw a potentially serious disruption in the economic structure of animal agriculture. These disruptions could probably take the form of regional shifts, vertical integration and scale specific changes in animal production. Currently, the pace of agricultural systems change is faster than the generational pace that has existed in the past. The speed of change brings problems in people keeping up with the new skills required. He asked: (1) who would bear the costs of such changes?, (2) What will be done to help people displaced by these shifts?, (3) Should USDA take some responsibility for retraining programs to minimize these effects?

One person pointed out that existing market factors create inertia in the public's acceptance of new products. He illustrated his point by noting the poor acceptance of beefalo meat in the market place. What are the factors that are operating regarding this poor acceptance? Is it because this meat is from a hybrid animal and people are squeamish about the hybrid aspect? If this implied a general squeamishness on the part of the U.S. public regarding novel meat products, will these same factors play a significant role in consumer acceptance of transgenic meat products? It was mentioned that a counter force

¹²The farmer's views, that the author has heard expressed at various meetings, are very accepting of the concept and realities of biotechnology and engineered seeds and animals.

may be food fads. One person stated that the only way to overcome consumer barriers may be to offer a product so superior that people would be foolish not to buy it. In other words, make such a product a "food fad". Research into the factors that determine consumer choices may be useful for USDA produced educational materials about the unique food products.

An overshadowing factor in the whole marketing stage will be the 17 year limit on patents. Can all the preparation of the public be done within the market window to allow a company to retrieve their costs spent on safety testing, scaling up and marketing to producers and consumers.

In summary, drastic changes in an agricultural system will obviously have economic repercussions starting with the producer, the processor and the marketer. Some projected impacts are inherent in any system changes, others will be unique to transgenic animals and the resulting products. An important factor in the success or failure will rest with the consumer.

Ecology. Although livestock animals are a focus for a variety of applications of transgenic technology, research is currently being conducted on other species such as food fish. Genetically engineered food fish raise some unique interesting and potentially broad reaching ecological concerns.

One ecological concern is the potential for hybridization between transgenics and wild species, in the event individuals escape containment systems. Obviously, genes used for modifying domestic populations could be very undesirable if transferred to feral populations. The escape of large livestock species may not be of great concern since they are easily contained and easily captured, but geographic location and terrain may affect ease of capture and be important here too.¹³ Release and/or escape scenarios may have to be developed on a case-by-case basis with the factors of climate, terrain, presence or absence of wild species, etc., in order to prepare safeguards.

¹³ There are known populations of feral pigs, goats, equine, and sheep in parts of the U.S. The following 2 articles deal with this topic: R.L Degner, L.W. Rodan, W.K. Mathis, and E.P.J. Gibbs "The recreational and commercial importance of feral swine in Florida." Industry Report - Florida Agricultural Market Research Center, Food and Resource Economics Department, Agricultural Experiment Station 82-1 (Jan 1982). National Park Service "Death Valley National Monumnet, California/Nevada." Department of the Interior (September 1981).

Such a scenario for fish could be similar to the one presented by the aquaculturist, illustrates some of the possible ecological impacts of engineered fish species in an aquaculture system. Fish can potentially escape via a number of natural disasters, activities of aquatic birds and human tampering. If escape occurs, the nature of the transferred gene and its function will be the important determinant of the seriousness of the impact on a native population or natural aquatic system. If the altered fish can interbreed or are more vigorous than indigenous species they could upset delicate aquatic ecology. To deal with this problem, lethal genes and sterility via triploidy and heat shock have been developed in fish, but to date the results are not 100% effective. With the state of current technology, there will always be a chance that some escaped individuals will reproduce or hybridize in a natural ecosystem.

Engineering warm water fish to live in a colder climate may allow for a major expansion of aquaculture to sections of the country that do not presently have an aquaculture industry. This could mean an additional economic gain product for the local economy base but potential long term ecological deficit. For example there has been an increase in waterfowl populations to "nuisance" levels.¹⁴ in areas of the South where aquaculture systems are concentrated. Could this phenomenon also happen in other areas? Water resources could be changed or polluted because of damming water courses for aquaculture systems and polluting drainage waters (nutrient-rich or contain algacides or residues of therapeutic compounds). To prevent the worst case scenarios, the aquaculturist suggested that the complexities of the soil types and aquifers will need to be carefully studied prior to the establishment of a large aquaculture program in regions where such systems have not been feasible.

Ecological and/or environmental impacts due to transgenic animals may be many and varied and possibly serious. On the other hand possibly the technology offers opportunities for producing animals that are specifically designed to integrate into a sustainable agriculture system. It was recommended that a careful extensive study of the local ecology, environment, and flora and fauna of an area may be needed before introducing systems based

¹⁴ For more information the reader is referred to the following articles: E. Hanebrink and W. Byrd "Predatory birds in relation to aquaculture farming" Aquaculture Magazine 15(2):47-51 (1989) and H.L. Schramm Jr.; M.W. Collopy and E.A. Okrah "Potential problems of bird predation for fish culture in Florida." Range and Wildlife Management. 49(1):44-49 (1987).

on GEA's.

Societal Concerns--Animal Rights, Ethics. There were a number of concerns that can be considered religious and ethical in nature. Some of them have been raised by "animal rights" advocates and centers around the definition of "right". The economist provided the following theoretical regarding "rights". "Humans have developed a mode of structuring human relationships that include 'rights' but along with these 'rights', they assume responsibilities. These [rights] are human inventions." The "animal rights" advocates extend these rights beyond the human sphere to animals. Since these issues have been raised, our society is struggling with the relative importance of animals and appropriate levels of animal care usage. The economist thinks the U.S. public may desire a consensus on ethical questions and the definition of the rights of animals, but the pluralistic nature of our society makes consensus almost impossible which results in some level of discomfort for most individuals. The "animal rights movement" has had an effect on policies and regulations and will continue to have an effect. USDA Administrators and others who set policy regarding animals are advised to stay in touch with the movement to assess and prepare for potential impacts on the government.

Illustrating the plurality of opinions, interviews provided the following window to the psyche of the American public: "Mysteries of life should stay mysteries"; "The universe and everything in it is God's work"; "If God wanted plants to walk He would have given them legs and made animals green"; "Scientists are playing God"; and "Nature is perfect, so don't tinker with it!" Some individuals interviewed mentioned a concept called Natural Rights--that nature should not be exploited without limits. The sanctity of species and man's tampering with them may have religious overtones, but there is a complicating belief, by some, that natural is "good" and "safe", and that "messing" with the present genomes will lead to "bad" animals.

Many religious leaders are struggling to evaluate this new technology within the context of past history and established precedents of their faith. Such leaders can influence the directions of public opinions on a variety of issues. It was recommended that their concerns should be recognized and addressed by the USDA.

The types and source of genes used was a concern. It was explained that

the use of human genes in animals, animal genes in other animals or plants and animal genes in humans, begins to blur the differences that have been traditionally used to classify life forms. "Tinkering" with the genome of primates, and whether eating meat with human genes is a form of cannibalism, seemed especially troublesome prospects for most interviewees. A number of questions were raised regarding ethical behavior for government:

- ◆ Will the government act honestly regarding regulating the risks of research, environmental release and products?
- ◆ Will information released for the public be credible? Will negative issues be dealt with honestly?
- ◆ Are there areas of research that will be declared restricted or off limits, (e.g. biological warfare or using human genes in primates which could alter intelligence)?
- ◆ Who or what governmental body will determine if proposed research is needed, scientifically valid, unethical or frivolous?
- ◆ If the research results doom an animal to pain--what level of return would justify their painful existence?
- ◆ Will government research and policy planning be short-term and self-serving?
- ◆ How will agencies and institutions deal with unanticipated negative events?
- ◆ Will we allow for the exploitation of third world countries where laws may be less restrictive and protective?
- ◆ How much responsibility, for all aspects of the use of this technology, will researchers and government officials assume?

USDA obviously will have to address all or a few of the above questions.

Briefly, it was projected that it will be difficult to establish a consensus of

opinion and policies on these issues in the pluralistic U.S. society. But a more basic question that affects many of the issues raised above is--does man have the right to "tinker" with animals as they exist or should they be inviolate? If the answer is "yes", then what should the limits be?

Communication and Education. Education of the non-science literate public was on everyone's mind! One individual felt that the current method of problem solving in the government does not spend enough time on "defining the issues". Shortchanging this step in the educational process tends to lead to poor decision making which he felt leads to "bad" laws and unsatisfactory regulatory processes. Therefore, he feels increased energies should be spent on educating the public stressing scientific literacy, credibility, and effective methods of communication.

Scientific illiteracy was considered, by most interviewees, to be at a very high level in this country. For example, the researchers noted the public's lack of understanding of the concepts of classical animal breeding which needs to be comprehended before you can absorb the concepts of genetic engineering. The lack of an adequate scientific knowledge base makes it difficult for a government body, such as USDA, to present digestible scientific information to the general public. The lack of the science knowledge for informed public decision making sets the stage for emotionally based information being used to define, inflame and promote public fears against this new technology. To deal with informing the scientifically illiterate public regarding issues of genetic engineering, it may mean allocating departmental resources to understanding effective communication strategies for explaining the products of genetic engineering technologies.

From the point-of-view of the public, 2 issues of credibility were raised-- (1) the mystical position that the research community has in the public's eye, and (2) the perceived cover-up mentality of government agencies regarding past events like the chemical spill in Bhopal, India and the radioactive water vapor released at Three Mile Island. It is common knowledge that every technology has its' hazards, but how such disasters are handled by government officials, sets the stage for a climate of public suspicion regarding decision making and crisis management by government officials. One interviewee felt that there are new, increased levels of concern regarding credibility because adolescents of the 60's are now mainstream adults and influencing the culture because of their

Vietnam era experiences.

Everyone recognizes that credibility of government generated information probably is always going to be difficult to attain, but the interviewees suggested 6 strategies for improving credibility and the communication channels between the researcher, the federal agencies and the public.

(1) Departments in a position such as USDA's should organize symposia directed specifically to the media. One individual suggested that input from science writers regarding format and subject coverage for such symposia would ensure that appropriate information and clarification was provided. To prevent USDA from being biased, speakers from all sides of the issue should be invited to participate and plenty of time should be scheduled for questions.

(2) It was recommended that USDA utilize educational publications that have been produced by other organizations. The rationale behind such an activity is that information produced without an obvious vested interest may be seen as being less biased and therefore more credible. (The individual representing the biotechnology industry stated that organization has plans to distribute a biotechnology related document produced for precollege education in Europe. He would be happy to participate in cooperative efforts with the Department.)

(3) Some individuals suggested that USDA sponsor special public oriented educational programs.

(4) There were suggestions to expand the role of the USDA Extension Service to include educating the general public.

(5) Having scientists trained to appear in the media may help ameliorate the public's "ivory tower" image of researchers. (A researcher said he would like to have media training and wished USDA would routinely offer such training courses.

(6) Some fears on the part of the public may be easily dealt with if the public is informed that guidelines and regulations are being developed for the protection of human and animal health and the environment.

II. ADVICE REGARDING USDA PROGRAMS AND ADMINISTRATION

This section is a summary of the advisory comments that were made by the interviewees in response to the question: "What **advice** do you have for an administrator regarding transgenic animal research and the resulting products?" Most interviewees had plenty of advice to offer! The advisory responses fell into four major areas: research issues, USDA programs, USDA policies, and communication with the public. There is some overlap with portions of the material related above.

Research Issues. The need for a better understanding of factors that determine consumer perceptions and acceptance of food animal products was mentioned. The images of potentially "bad" products need to be dispelled in the public's mind, since these images may generate restrictive legislation at all levels.

Some interviewees suggested that:

- ◆ There should be greater efforts to coordinate research priorities and directions between USDA/Agricultural Research Service and CSRS/Cooperative State Research Service programs. High priority issues that should be addressed are; research needs such as food safety issues, hardiness of homozygous transgenic animals, knowledge of animal genome to allow for the use of desirable genetic material from nonhuman sources, environmental risks of escaped animals, and economic effects of transgenic animals and products on the consumer. Interdisciplinary approaches should be encouraged in some research areas for a more comprehensive exploration of problems.
- ◆ USDA should fund more social and philosophical research to better understand the complexities of decision making within the U.S. society.
- ◆ USDA should enhance understanding of our culture so that communication can be more effective within our own and the emerging world culture.

USDA Programs. Overwhelmingly, interviewees recommended that USDA expand programs that raise the scientific literacy of its constituency and the U.S. population. One individual felt that elementary through college students were the most important target audiences followed by farmers, media generators and the general public.

Elementary levels could be addressed through an expansion of an existing USDA program--Ag in the Classroom. Scientists should be involved in producing or supporting the development and use of biotechnology oriented lesson plans for the curriculums for elementary and high school students. (Several interviewees expressed distress that not only biotechnology is not taught, but general sciences and agricultural sciences/research are generally neglected or inadequately covered topics in current education.)

There are already a number of ways that farmers can be educated about the new technologies. Many farmers could be reached by the effective utilization of the many Extension Service and other educational programs and trade magazines directed to the agricultural community.

Suggestions for reaching the media are listed in the previous section.

Potential new directions for educating the general public would be collaborative sponsorship of more private/government efforts to educate the general public about agriculture and agricultural research. EPCOT Center was suggested as a model that could and should be duplicated elsewhere in the country.

Policy. It was a suggestion by several people that federal policies and/or guidelines be developed specifically for institutions conducting transgenic animal research. Such policies/guidelines should address euthanasia considerations, security programs, physical plant/facility needs for adequate care of "special animals", adequate training of personnel in handling, husbandry and care, and potentially unique biohazards for those working with transgenics.

Since the introduction of the first genetically engineered products for the consumer was considered by most of the interviewees to be a critical issue, some questioned in their own mind whether there should be policies regarding what and when biotech products are released to the consumer. Several people

referred to events that have happened regarding BST. Bovine somatotropin (BST) was the first obviously labelled biotech product and its' use has been promoted to produce an animal derived food product--milk. Various consumer groups have raised concerns about the health and safety of these BST derived products for humans and animals. Interviewees felt that BST¹⁵ is a test case which they feel raised the following questions regarding its use in animals and the resulting milk products.

- ◆ What factors have influenced the public responses?
- ◆ How have the responses of the public been related to the communication activities of USDA and the media?
- ◆ How have the research and regulatory agencies media communications and actions impacted on the publics view of the compound and its use?
- ◆ What could have been done differently to lessen the controversy that surrounds the use of BST in a dairy system?
- ◆ What role does the timing of product introduction play in public acceptance?
- ◆ How important was the milk surplus issue?
- ◆ How does the compound affect animal health?
- ◆ Are there unarticulated ethical issues involved in the controversy?

The answers to these questions might enlighten USDA and producers on how to introduce biotech food products in the future.

Several people thought that the public doubts the comprehensiveness and truth of public relations materials produced by those who have a vested interest

¹⁵For a bibliography of 376 citations of the recent literature detailing issues, physiology and management of BST the reader is referred to the following publication: Jean A. Larson (March 1992) "BST--Bovine Growth Hormone: January 1987--January 1992." Quick Bibliography; QB92-30.

in a product (i.e. researchers, government sponsors and private industry). It was suggested that it would be wise for USDA administrators to be very candid about products that are released, and attempt to provide consumer information from non-biased, independent sources. Departmental administrators should be candid regarding "the good and the bad" aspects of products and processes, and express their knowledge of public concerns. They should have the policies, regulations or programs in place that they can point to, to reassure the public that there are adequate protections.

One person felt that product releases should be very carefully chosen, for public acceptance. The Department might want to develop informal policies for first releases. Maybe first releases might have a higher acceptance rate if they are "lean, reduced cholesterol meat" or "disease and insect resistant animals". It was recommended such products have "all positives and no negatives".

An opposite position was taken by one interviewee who strongly felt that there should be no product policies. Let the marketplace decide the fate of the product! "USDA should not direct or orchestrate the types of products approved for consumers". A contrary point-of-view was raised that USDA policies are too influenced by agribusiness. The USDA administrators may have to decide whether the Department has a stake in determining the first product releases and set a policy of intervention or non-intervention. The current situation does appear to be heading for a crisis, and as the philosopher said, the Department should "be prepared for a crisis by understanding the legal, ethical, and philosophical issues before the crisis occurs". In other words, be proactive and have adequate comprehensive policies in place!

Recommendations--Communication. Almost everyone saw USDA administrators as spokespersons for the genetic engineering technology because most of the applications are projected to take place in plants and animals. Because they felt communication at these levels was so important, they offered the following "do's and don't's" for Departmental spokespersons:

DO'S:

- ◆ "Focus on the correct issues--benefits and low level of risk" of biotech products. Keep in mind that cost benefits from the scientist's

point of view may not be the same as those perceived by consumers.

- ◆ Emphasize the technology groundwork being laid by researchers such as: RFLP maps, the homology of the DNA between humans and animals, the increased control of insertion of DNA, lessons learned from laboratory studies, and the safe number of field trials that have been completed with genetically engineered plants.

- ◆ Educate the public with a lot of lead time by creating educable moments.

- ◆ Be sensitive to the concerns raised by the public, and be educated by the public. Engage in effective dialogue, don't avoid opportunities.

- ◆ Wholesale educational initiatives to outside groups.

- ◆ Use the Extension Service to help produce and distribute educational materials.

DONT'S:

- ◆ Don't publish photos of abnormal looking animals or photos of initial attempts that are not very successful in approaching the ultimate animal applications, or the results of poor photography.

- ◆ Don't gloss over negative issues. Be candid and state the steps being taken to insure public safety.

- ◆ Don't underestimate the prestige that Departmental administrators hold in most citizens' opinion. This is a precious commodity that could be ruined by a lack of candor. Once the reputation as a credible resource is lost, it is very difficult to reestablish it.

The philosopher gave some suggestions on dealing with activists that may be helpful. He suggested that there needs to be a basic understanding of the role assumed by the activists, which is to define the reasons for apprehension on the part of the public. In other words, the activists use their personal agendas as the basis for telling people what they should fear and why they

should be fearful. The philosopher feels that the following responses are appropriate in a dialogue with activists:

- ◆ Acknowledge that the public has concerns.
- ◆ Raise questions about what the issues really are. Concerns may not be as clear cut as the activists may be trying to make them.
- ◆ As a spokesperson for USDA never deny the existence of public concerns. This will get a very negative response that will be hard for the Department to overcome.
- ◆ If lines of controversy are drawn:
 - (1) Ascertain what issues are open to compromise.
 - (2) Discuss tradeoffs--animals versus people--then state the government's position.
- ◆ If compromise would destroy a value:
 - (1) State: "These are your values but they are not widely shared within our culture." If the group is doctrinaire, note that they appear to be speaking for a small group of people within the broader society.
 - (2) Realize that if the values of the general public are changing, the government programs may have to change to reflect that positional change, and USDA should anticipate what those value changes will be and consider if change is needed.

It is hoped that the information presented above can be of help to those individuals who are faced with decision making regarding many issues that relate to animals and products that are being developed with genetic engineering technology.

APPENDIX A

Selected Readings in Biotechnology and Genetically Engineered Animals

CONTENTS

General Articles on Biotechnology	30
Transgenic Animals	32
Animal Welfare	36
Bioethics	36
Ethics	37
Risk Assessment	38
Patenting	39
Legislation/Regulation	40
Author Listing	41

GENERAL ARTICLES ON BIOTECHNOLOGY

001

Baumgardt, B.R. and Marten, M.A. 1991. *Agricultural Biotechnology: Issues and Choices* Purdue University, Agricultural Experiment Station, West Lafayette, IN.

002

Moffat, A.S. 1991. "Trangenic animals may be down on the pharm." *Science* 254:36-37.

003

Quayle, D. 1991. *The President's Council on Competiveness Report on National Biotechnology Policy* Washington, DC.

004

Naisbitt, J. and Aburdene, P. (eds.), 1990. *Megatrends 2000: Ten New Directions for the 1990's* William Morrow and Co. Inc., pp. 241-269.

005

Purchase, H.G. and MacKensie, D.R. 1990. *Agricultural Biotechnology: Introduction to Field Testing* Office of Agricultural Biotechnology, U.S. Department of Agriculture.

006

Animal Production and Health Division, FAO. 1989. *Biotechnology for Livestock Production* Plenum Press.

007

Suzuki, D. and Knudtson, P. 1989. *Genetics: The Clash Between the New Genetics and Human Values* Harvard University Press.

008

Klassen, W. 1989. "Public concerns regarding applications of biotechnologies." *Biodeterioration* 2:7-17.

009

Hoban, T.J. 1989. "Sociology and biotechnology: Challenges and opportunities." *Southern Rural Sociology* 6:45-63.

010

Tiedje, J.M.; Colwell, R.K. and Grossman, Y.L. 1989. "The planned introduction of genetically engineered organisms: Ecological considerations and recommendations." *Ecology* 70(2):298-315.

011

USDA, 1988. *Agricultural Biotechnology and the Public. A Report on Four Regional Information Conferences* Summary prepared by the Office of Public Liaison, USDA, Washington, DC.

012

George, P. 1988. "Biodiversity and biotechnology." *Journal of Agricultural Ethics* 1:175-192.

013

U.S. Congress, Office of Technology Assessment, 1987. *New Developments in Biotechnology - Background Paper: Public Perceptions of Biotechnology* OTA-BP-BA-45.

014

Panem, S. (ed.), 1985. *Biotechnology: Implications for Public Policy* Brookings Institute, Washington, DC.

015

Miller, J.D. 1985. *The Politics of Emerging Issues: A Analysis of the Attitudes of Leaders and Larger Publics Toward Biotechnology*, A paper presented to the 1985 Annual meeting of the American Political Science Association, New Orleans, LA.

TRANSGENIC ANIMALS

016

Hansel, W. and Godke, R.A. 1992. "Future prospectives on animal biotechnology." *Animal Biotechnology* 3(1):111-137.

017

Havenstein, G.B., Crettenden, L.B., Petite, J.N., Qurcshi, M.A., and Foster, D.N. 1992. "Application of biotechnology in the poultry industry." *Animal Biotechnology* 3(1):15-36.

018

Larson, J.A. 1992. "BST - bovine growth hormone Januray 1987-January 1992." *Quick Bibliography* QB 92-30, National Agricultural Library, Beltsville, MD.

019

Larson, J.A. 1992. "PST - porcine growth hormone January 1979-January 1992." *Quick Bibliography* QB 92-31, National Agricultural Library, Beltsville, MD.

020

McLaren, D.G. 1992. "Biotechnology transfer: A pig breeding company perspective." *Animal Biotechnology* 3(1):37-54.

021

Rexroad, Jr., C.E. 1992. "Transgenic technology in animal agriculture." *Animal Biotechnology* 3(1):1-13.

022

Weber, G.M. 1992. "Factors influencing technology transfer." *Animal Biotechnology* 3(1):155-163.

023

Fischetti, M. 1991. "A feast of gene-splicing down on the fish farm." *Science* 253:512-513.

024

Glasser, V. 1991. "DNX Corporation develops transgenic pigs capable of manufacturing human hemoglobin." *Genetic Engineering News* 11(7):1-37.

025

Pursel, V.G.; Bolt, O.J.; Miller, K.F.; Pinkert, C.A. and Hammer, R.E. 1990. "Expression and performance in transgenic pigs." *Journal of Reproduction and Fertility Supplement* 40:235-245.

026

Pursel, V.G.; Hammer, R.E.; Bolt, D.J.; Palmiter, R.D. and Brinster, R.L. 1990. "Integration, expression and germline transmission of growth related genes in pigs." *Journal of Reproduction and Fertility Supplement* 41:77-87.

027

Rexroad, Jr., C.E. 1990. "Near and long-term applications of transgenics in agriculture." *Proceedings of the Maryland Nutrition Conference for Feed Manufacturers* pp. 102-106.

028

Kapuscinski, A.R. and Hallerman, E.M. 1990. "Transgenic fish and public policy: Anticipating environmental impacts of transgenic fish." *Fisheries* 15(1):2-11.

029

Hallerman, E.M. and Kapuscinski, A.R. 1990. "Transgenic fish and public policy: Regulatory concerns." *Fisheries* 15(1):12-20.

030

American Veterinary Medical Association. 1990. *Veterinary Perspectives on Genetically Engineered Animals* Proceedings of a forum sponsored by AVMA, September 19-20, 1988, Washington, DC.

031

Pursel, V.G.; Pinkert, C.A.; Miller, K.F.; Bolt, D.J. and Campbell, R.G. 1989. "Genetic engineering of livestock." *Science* 244:1281-1288.

032

Rexroad, Jr., C.E. 1989. "Near and long-term applications of transgenics in agriculture." In: *Proceedings of the Maryland Nutrition Conference for Feed Manufacturers* pp. 102-106.

033

Larson, J. and Nanis, S. 1988. "Biotechnology: Methodologies involved in the production of transgenic animals." *Special Reference Brief* SRB 88-10, National Agricultural Library, Beltsville, MD.

034

Mellon, M. 1988. *Biotechnology and the Environment: A Primer on the Environmental Implications of Genetic Engineering* National Wildlife Federation.

035

Van Brunt, 1988. "Molecular farming: Transgenic animals as bioreactors." *Biotechnology* 6:1149-1154.

036

Enibolopov, G.N. and Kuzin, B.A. 1987. "Prospects for use of transgenes in livestock improvement." *Biotekhnologiya* 3:358-360.

037

Smith, C.; Meuwissen, T.H.E. and Gibson, J.P. 1987. "On the use of transgenes in livestock improvement." *Animal Breeding Abstracts* 55(1):1-10.

038

Brinster, R.L. and Palmiter, R.D. 1986. "Introduction of genes into the germline of animals." *Harvey Lecture Series* Liss Publishing Co., New York, NY; 80:1-38.

039

Mercier, J.C. 1986. "Genetic engineering applied to milk producing animals: Some expectations." *Exploiting New Technologies in Animal Breeding: Genetic Development* Smith, C.; King, J.W.B. and McKay, J.C. (eds.), Published on behalf of the Commission of the European Communities, Oxford Press.

040

Palmiter, R.D. 1986. "Germline transformation of mice." *Annual Review in Genetics* 20:465-499.

041

Gordon, J.W. and Ruddle, F.H. 1985. "DNA-mediated genetic transformation of mouse embryos and bone marrow - a review." *Gene* 41:121-136.

042

Palmiter, R.D. and Brinster, R.L. 1985. "Transgenic mice." *Cell* 41:343-345.

043

Wagner, E.F. and Stewart, C.L. 1985. "Integration and expression of genes introduced into mouse embryos." *Experimental Approaches to Mammalian Embryonic Development* Rossant, J. and Pederson, R.A. (eds.), Cambridge University Press.

044

Brinster, R.L. and Palmiter, R.D. 1982. "Introduction of foreign genes in animals." *Trends in Biochemical Science* 7:438-440.

045

Palmiter, R.D.; Brinster, R.L.; Hammer, R.E.; Trumbauer, M.E. and Rosenfeld, M.G. 1982. "Dramatic growth of mice that develop from eggs microinjected with metallothionein-growth hormone fusion genes." *Nature* 300:611-615.

046

Gordon, J.W.; Scangos, G.A.; Plotkin, D.J.; Barbosa, J.A. and Ruddle, F.H. 1980. "Genetic transformation of mouse embryos by microinjection of purified DNA." *Proceedings of the National Academy of Science USA* 77:7380-7384.

ANIMAL WELFARE

047

Grandin, T. 1991. "Biotechnology and animal welfare." In: *Animal Biotechnology and the Quality of Meat Production* Fiems, L.O., Cottyn, B.G. and Demeyer, D.I. (eds.), Elsevier Science Publishers B.V., Amsterdam.

048

Fox, M.W. 1988. "Genetic engineering biotechnology." *Applied Animal Behaviour Science* 20:83-94.

049

Murphy, C. 1988. "The 'New Genetics' and the welfare of animals." *New Scientist* 120(1642):20-21.

050

Fox, M.W. 1980. *Animal Welfare Concerns of Genetic Engineering Biotechnology* Humane Society of the United States, Washington, DC.

BIOETHICS

051

Clauser, K.D. 1989. "Bioethics." *Contemporary Issues in Bioethics* Beauchamp, T.L. and Walters, L.R. (eds.), 3rd edition, Wadsworth Publishing Co., pp. 54-64.

052

Englehardt, Jr., H.T. 1989. "The emergence of a secular bioethics." *Contemporary Issues in Bioethics* Beauchamp, T.L. and Walters, L.R. (eds.), Wadsworth Publishing Co., pp. 65-72.

ETHICS

053

Warmbrodt, R.D. 1991. "Biotechnology and bioethics January 1979-March 1991." *Quick Bibliography* QB 91-112, National Agricultural Library, Beltsville, MD.

054

Advisory Committee on Ethics and Biotechnology in Animals. 1990. *Ethics and Biotechnology in Animals* A report to the Minister of Agriculture, Nature Management and Fisheries, Wageningen, Netherlands, (English Translation).

055

Grendel, S.M.; Kline, A.D.; Warren, D.M. and Yates, F. 1990. *Agricultural Bioethics: Implications of Agricultural Biotechnology* Iowa State University Press.

056

Plien, L.C. and Weber, D.J. (eds.), 1989. *Biotechnology and Ethics: Social Change and Human Values* Proceedings of a conference held at University of Missouri, December 6-7, 1989 University of Missouri, Columbia, MO.

057

Farrell, K.R. 1989. "Contemporary issues: Ethics in agricultural research." *Journal of Production Agriculture* 2(3):193-196.

058

Wachbroit, R. 1989. "Ethical issues related to crossing species barriers." *Studies in Technology and Social Change* Iowa State University, Series No. 10:23-33.

059

Church, R.B. 1988. "Are problems posed by genetically engineered animals?" *Applied Animal Behaviour Science* 20(1&2):73-82.

060

Thompson, B. 1988. "Ethics in agricultural research." *Journal of Agricultural Ethics* 1:11-20.

061

Beverdors, W.D. and Castagno, J.R. 1987. "The ethics of biotechnology." *Agrologies* 16(4):20-21.

062

Bone, E. 1987. "The ethical and social dimensions of biotechnologies." *Industrial Biotechnology in Europe: Issues for Public Policy* Davies, D. (ed.), Francis Pinter (publisher), pp. 99-108.

063

deJong, O.J. 1987. "Ethische aspecten von Biotechnologie." *Tijdsch Diergeneeskde* 112(2):88-97.

064

Dixon, B. 1984. "Engineering chimeras for Noah's Ark." *The Hastings Center Report* 14(2):10-12.

RISK ASSESSMENT

065

Ginzburg, L.R. (ed.), 1991. *Assessing Ecological Risks of Biotechnology* Butterworth-Heinemann, Boston, MA; 379 pp.

066

Levin, M.A. and Strauss, H.S. (eds.), 1991. *Risk Assessment in Genetic Engineering* McGraw-Hill, New York, NY; 404 pp.

067

Warmbrodt, R.D. 1991. "Biotechnology: Risk assessment January 1986-February 1991" *Quick Bibliography* QB 91-79, National Agricultural Library, Beltsville, MD.

068

Berkowitz, D.B. 1990. "The food safety of transgenic animals." *Biotechnology* 8:819-825.

069

Zeckhauser, R.J. and Viscusi, W.K. 1990. "Risk within reason." *Science* 248:559-563.

070

Krimsky, S.; Bergman, K.; Connell, N.; Shulman, S. and Wilker, N. 1989. "Controlling risk in biotech" *Technology Review* 92(5):62-70.

PATENTING

071

Warmbrodt, R.D. 1991. "Biotechnology: Patenting issues January 1979-December 1990" *Quick Bibliography* QB 91-77, National Agricultural Library, Beltsville, MD.

072

Auerback, J.I. 1989. "Transgenic animals and patenting." *ATCC Quarterly Newsletter* 9(2):1-2,4,9-11.

073

Lesser, W.H. (ed.), 1989. *Animal Patents: The Legal, Economic and Social Issues* Proceedings of a symposium held at Cornell University, December 5-6, 1988. Stockton Press.

074

Wachbroit, R. 1989. "Ethical issues concerning the patenting of animals" *Personal Communication*.

075

Bent, S.A.; Schwaab, R.L.; Conlin, D.G. and Jeffery, D.D. 1987. *Intellectual Property Rights in Biotechnology Worldwide* Stockton Press.

076

U.S. Congress, Office of Technology Assessment. 1987. *New Developments in Biotechnology: Patenting Life* Office of Technology Assessment, OTA-BA-370. Washington, DC.

LEGISLATION/REGULATION

077

Batter, M. 1991. "How Europe regulates its genes." *Science* 252:1366-1368.

078

Warmbrodt, R.D. 1991. "Biotechnology: Legislation and regulation January 1979-February 1991." *Quick Bibliography* QB 91-80, National Agricultural Library, Beltsville, MD.

079

Industrial Biotechnology Association. 1989. *Survey of State Government Legislation on Biotechnology August 1, 1989* Washington, DC.

AUTHOR LISTING

- | | |
|------------------------------------------------------------------|---------------------------------------------|
| Aburdene, P. 004 | Farrell, K.R. 057 |
| Advisory Committee on Ethics and
Biotechnology in Animals 054 | Fischetti, M. 023 |
| American Veterinary Medical
Association 030 | Foster, D.N. 017 |
| Auerback, J.I. 072 | Fox, M.W. 048, 050 |
| Barbosa, J.A. 046 | George, P. 012 |
| Batter, M. 077 | Gibson, J.P. 037 |
| Baumgardt, B.R. 001 | Glasser, V. 024 |
| Bent, S.A. 075 | Godke, R.A. 016 |
| Bergman, K. 070 | Gordon, J.W. 041, 046 |
| Berkowitz, D.B. 068 | Grandin, T. 047 |
| Beversdorf, W.D. 061 | Grendel, S.M. 055 |
| Bolt, D.J. 026, 031 | Grossman, Y.L. 010 |
| Bolt, O.J. 025 | Hallerman, E.M. 028, 029 |
| Bone, E. 062 | Hammer, R.E. 025, 026, 045 |
| Brinster, R.L. 026, 038, 042, 044,
045 | Hansel, W. 016 |
| Campbell, R.G. 031 | Havenstein, G.B. 017 |
| Castagno, J.R. 061 | Hoban, T.J. 009 |
| Church, R.B. 059 | Industrial Biotechnology Association
079 |
| Clauser, K.D. 051 | Jeffery, D.D. 075 |
| Colwell, R.K. 010 | Kapuscinski, A.R. 028, 029 |
| Conlin, D.G. 075 | Klassen, W. 008 |
| Connell, N. 070 | Kline, A.D. 055 |
| Crettenden, L.B. 017 | Knudtson, P. 007 |
| deJong, O.J. 063 | Krimsky, S. 070 |
| Dixon, B. 064 | Kuzin, B.A. 036 |
| Englehardt, Jr., H.T. 052 | Larson, J.A. 018, 019, 033 |
| Enibolopov, G.N. 036 | MacKensie, D.R. 005 |



Marten, M.A. 001	Tiedje, J.M. 010
McLaren, D.G. 020	Trumbauer, M.E. 045
Mellon, M. 034	
Mercier, J.C. 039	
Meuwissen, T.H.E. 037	U.S. Congress, Office of
Miller, J.D. 015	Technology Assessment 013, 076
Miller, K.F. 025, 031	USDA 011
Moffat, A.S. 002	
Murphy, C. 049	Van Brunt 035
	Viscusi, W.K. 069
Naisbitt, J 004	
Nanis, S. 033	Wachbroit, R. 058, 074
	Wagner, E.F. 043
Palminter, R.D. 026, 038, 040, 042, 044, 045	Warmbrodt, R.D. 053, 067, 071, 078
Panem, S. 014	Warren, D.M. 055
Petitte, J.N. 017	Weber, G.M. 022
Pinkert, C.A. 025, 031	Wilker, N. 070
Plien, L.C. 056	
Plotkin, D.J. 046	Yates, F. 055
Purchase, H.G. 005	
Pursel, V.G. 025, 026, 031	Zeckhauser, R.J. 069
Quayle, D. 003	
Qurcshi, M.A. 0117	
Rexroad, Jr., C.E. 021, 027, 032	
Rosenfeld, M.G. 045	
Ruddle, F.H. 041, 046	
Scangos, G.A. 046	
Schwaab, R.L. 075	
Shulman, S. 070	
Smith, C. 037	
Stewart, C.L. 043	
Suzuki, D. 007	
Thompson, B. 060	

